REMARKS/ARGUMENTS

This paper is submitted in response to the Office Action dated September 12, 2006. Claim 1 has been amended, without intending to abandon or to dedicate to the public any patentable subject matter. Claim 29 is new. Accordingly, Claims 1-26, 28 and 29 are now pending. As set forth herein, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Claims 1-3, 5-22 and 28 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6, 264, 629 to Landau ("Landau '629"). In addition, Claim 1-22 and 28 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent Application No. 2001/0004681 to Landau ("Landau '681"). Claims 17-22, 23 and 24-26 stand rejected under 35 U.S.C. § 103 as being unpatentable over Landau '629, U.S. Patent Application No. 2003/0093030 to Landau ("Landau '030") and/or U.S. Patent No. 6,752,781 to Landau et al. ("Landau '781"). In order for a rejection under 35 U.S.C. § 102 to be proper, each and every element as set forth in a claim must be found, either expressly or inherently described in a single prior art reference. (MPEP § 2131.) In order to establish a *prima facie* case of obviousness under § 103, there must be some suggestion or motivation to modify the reference or to combine the reference teachings, there must be a reasonable expectation of success, and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.) However, all of the claim elements cannot be found in the cited references, whether those references are considered alone or in combination. Accordingly, reconsideration and withdrawal of the rejections of the claims as anticipated by or obvious in view of the cited references are respectfully requested.

The claimed invention is directed to a disposable gas-powered needle-free injection device having an axially-movable inner housing which can be used to draw a desired dose of liquid medicament into the device ready for delivery into the patient. As set forth in the amended claims, the desired dose can be an amount selected by a user. Previously, such disposable gas-

powered needle-free devices utilised a pre-filled and sealed cartridge or cylinder of liquid medicament which is preloaded into the device.

U.S. Pat. No. 6,264,629 discloses "a drug injection cartridge which provides a cylinder of liquid medication to be injected" (Landau '629, abstract). As stated in the field of the invention section of Landau '629: "Particularly, this invention relates to . . . a hand-held injector having a pre-filled drug cartridge sealingly carrying injectable medication." (Landau '629, column 1, lines 15-18). There is no teaching whatsoever in Landau '629 regarding the possibility of adapting such a device to permit dosing by the patient. Regarding the volume of medicament to be delivered, the only teaching is that the dose is determined by the size of pre-filled drug injection cartridge 14. (Landau '629, column 4, lines 29-40.)

U.S. Application Publication No. 2001/0004681 is a continuation in part of Landau '629 and the above paragraph applies equally here. In particular, Landau '681 discusses the use of an injection cartridge 14 that is manufactured and filled at a drug company. (Landau '681, paragraph 45.) Therefore, there is no teaching in Landau '681 regarding the possibility of adapting such a device to permit the patient to select and draw a desired dose into the injection apparatus.

U.S. Application Publication No. 2003/0093030 discloses a disposable gas-powered needle-free injection device with or using pre-filled medicament amounts. For example, the injector is described as being stored or shipped in a way to prevent contamination of an injectate in the storage chamber 58. Accordingly, the chamber is pre-loaded with medicament before being shipped to the patient. Alternatively, Landau '030 discusses a storage sleeve 146 that typically takes the form of a glass cylinder and is also pre-filled before shipping. (Landau '030, paragraphs 28, 37-38, Figs. 6-8). Therefore, unlike the claimed invention, Landau '030 does not allow a user to draw a selected does into the device.

U.S. Patent. No. 6,752,781 is directed to a durable hypodermic jet injector. According to Landau '781, the patient attaches a medicine vial from which the required dose is drawn into the injection cylinder 14 by causing a a ram 26 and injection piston to move rearwardly (Landau '781, column 5, lines 1-8, Fig. 3). Unlike Landau '781, the claimed invention features an inner housing that is drawn away from the nozzle to cause the dose to be drawn in. The piston 16 and

the associated ram 26 of Landau '781 are not an "inner housing" as claimed. Additionally, Landau '781 does not teach, suggest or describe the claimed cooperating guide means.

In the Office Action dated September 12, 2006, the Examiner noted that Claim 1 as originally filed did not require that the dose be a variable selectable dosage. In the amendments set forth above, Claim 1 has been amended to now recite that " the desired dose can be an amount selected by a user from within a range of doses." Therefore, it is submitted that the rejections of Claim 1 as anticipated should be reconsidered and withdrawn for at least this reason.

In addition, Claim 1 recites other features that are not taught, suggested or disclosed by the cited references. For example, Claim 1 recites "an inner housing located at least partly within the outer housing and being selectively axially movable away from said nozzle." None of the cited references teach, suggest or describe an inner housing axially movable away from a nozzle that is at least partly within the outer housing as claimed. In addition, amended Claim 1 recites "cooperating guide means on said inner and outer housings . . . wherein said axial movement of the inner housing is guided by said cooperating guide means to enable a desired dose of medicament to be drawn into said nozzle, ready for injection." None of the cited references teach, suggest or describe cooperating guide means as recited by amended Claim 1. Accordingly, the rejections of Claim 1 as anticipated should be withdrawn for at least these additional reasons.

A number of the dependent claims recite additional patentable subject matter. For example, Claim 2 recites that the injection device further comprises an indication of the dose of medicament which is drawn into the device. The Office Action cites to Landau '629, and in particular to projection 24 with respect to this feature of Claim 2. However, the projection 24 of Landau '629 does not provide an indication of the dose of medicament drawn into the device. Instead, the projection 24 cooperates with a blocking pin to prevent body portions of the Landau device from being rotated relative to one another except in a defined direction. Moreover, since Landau '629 is directed to a device that is pre-filled, there is no selection of a desired dose by a user to be indicated. (See Landau '629, column 4, lines 54-67; column 6, lines 15-22.) Therefore, for at least these additional reasons, the rejections of Claim 2 should be reconsidered and withdrawn.

Claims 3 and 4 depend from Claim 2, and therefore should be allowed for at least the same reasons that Claim 2 should be allowed. In addition, Claim 3 recites that the dose indication comprises a visible scale. There is no visible scale disclosed by the cited references. Instead, the references discuss alternately displaying the word "injection" or the word "storage."

As the cited references do not describe a visible scale, Claim 3 should be allowed for at least this additional reason.

Claim 4 depends from Claim 2, and recites that the "dose indication comprises an audible indication of the dose." This feature does not appear in the cited references. In particular, the portion of the Landau '681 reference cited to for this feature discusses a "snap" sound as an indication that the device is ready to effect an injection. (Landau '681, paragraph 82.) However, there is no disclosure by the Landau references of an audible indication of the dose as claimed. Accordingly, Claim 4 should be allowed for at least this additional reason.

Claim 5 recites that the "guide means comprises a substantially helical groove on said outer housing and a corresponding protrusion on said inner housing." As specified by Claim 1, the cooperating guide means enable a desired dose of medicament to be drawn into the nozzle ready for injection. The cited references do not teach, suggest or describe guide means with a helical groove to enable medicament to be drawn into the nozzle of an injection device. Accordingly, for at least this additional reason, Claim 5 should be allowed.

Claims 6-10 generally depend from Claim 5, and therefore should be allowable for this additional reason. In addition, Claim 6 recites that the protrusion of the guide means "comprises a substantially helical arrangement of discrete teeth, having pits there between." There is no such disclosure in the Landau reference. Indeed, the feature of the Landau references cited in connection with this claim element in the Office Action comprises conventional threads 64. (Landau '629, column 7, lines 22-30; Landau '681, paragraph 56.) Claim 7 further recites that the injection device comprises "an indication of the dose of medicament which is drawn into the device and a flexible indexer tab which can ride over said teeth in order to provide said dose indication." For this feature, the Office Action recites to the projection 24. However, the projection 24 of Landau does not ride over any teeth, and is not described as being flexible. Accordingly, for at least these additional reasons, Claim 7 should be allowed.

Claim 29 is new, and recites that the gas cylinder is located within the inner housing. The cited references do not teach, suggest or disclose an inner housing that is selectively axially movable away from the nozzle of an injection device, and that houses a gas cylinder. Accordingly, Claim 27 should be allowed for at least this additional reason.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

SHERIDAN ROSS P.C.

Date: March 12, 2007

By: _____

Bradley M. Knepper
Registration No. 44,189
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141
(303) 863-9700